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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Penfold	
Application No.: 09/557,955	Group Art Unit: 1645
Filed: 4/25/2000	Examiner: Patricia Ann Duffy
Title: Assay Reagents and Devices	Confirmation No. 8900
Attorney Docket No.: IMIN.P-027	

REPLY BRIEF FOR APPELLANT

This Reply Brief is filed in support of Applicants' Appeal from the final rejection mailed 3/27/2003 and in response to the Examiner's Answer mailed September 21, 2004.

In the Official Action of March 27, 2003, the Examiner's explanation of the rejection of claims 2-11 under 35 USC § 112, second paragraph is very limited. In the Examiner's Answer, however, the Examiner set forth nearly two pages of assertions in connection with this rejection. These are new arguments to which Applicants are entitled to respond.

In the Examiner's Answer, the Examiner persists in the arguments that claims dependent on a Jepson format claim must make it clear whether the added limitation is part of the preamble or part of the improvement. For example, in the passage bridging paragraphs 6 and 7, the Examiner asserts that "the dependent claims must make it clear if the improvement is amended or the preamble." The Examiner has not cited any law, rule or case to support this

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November 10, 2004
Date of Signature

argument. Instead, she states that in a Jepson claim, the preamble is admitted prior art, and the improvement defines what is new, and that a claim can only be definite if it is clear "as to what Applicant's improvement really is." (Examiner's Answer, Page 7). Nothing in 35 USC § 112, second paragraph, however, requires clarity as to the improvement. The statute requires that the scope of the **invention**, which is defined by the whole claim, be clear and definite. Furthermore, the preamble/improvement clause format set forth in 37 CFR § 1.75 (e) specifically refers to independent claims, and does not mention dependent claims. The Examiner is therefore applying a standard which has no basis in the law, and the rejection should be reversed.

Turning next to the anticipation rejection, the Examiner has changed her position between the Office Action and the Examiner's Answer. In the Official Action, of March 27, 2003, the Examiner stated that "due to the Jepson format of the claim, the limitations outside of the labeled reagent comprising a direct particulate label co-sensitized with a first specific binding reagent having specificity for the analyte and a non-specific protein which can participate in a control reaction" were not taken into account. (Office Action, Page 4) Now, the Examiner says that when the preamble is taken into account, the claim is still anticipated, and states that "it is unclear what element of the preamble does not view as being taught by May et al." This change of position justifies a further response by Applicants.

As a first matter, it must be observed that the Examiner is still failing to consider the claimed subject matter as a whole, and continues to pick the claim apart, by asking what part of the preamble is not disclosed in May et al. In fact, the preamble of Applicants claim provides the context in which the scope of the claims, and the improvement clause are to be considered. The preamble in claim 9 recites a device in which a labelled reagent is carried into a detection zone and a control zone, with binding of the labelled binding reagent at these zones revealing the assay result. The improvement lies in the specific character of the labelled binding reagent.

May discloses a labeled reagent that migrates and can be bound in the detection zone or a control zone. (See Col. 11, lines 45-60) However, this reagent is different from the presently claimed reagent because the reagent is an anti-hCG antibody, which binds to the analyte. This antibody participates in both the detection and the control reaction. In contrast, in the device of

claim 9, the reagent has two types of attachments on a particulate label (cosensitization), one of which binds the analyte, and the other of which binds in the control reaction but which is not involved in binding in the presence of analyte at the detection zone.

In the example in Col. 15 of May et al. specifically cited by the Examiner, colloidal gold is used as the label, and the antibody is an anti-hCG antibody. BSA is added for the sole purpose of blocking extra binding sites on the gold particles. There is no disclosure in May of a control zone that binds to BSA, and this is why the Examiner's failure to take into account the preamble in the first instance, and continued failure to take into account the claimed invention as a whole, should be deemed fatal to the anticipation rejection. May et al. simply does not disclose a device in which the a particulate label has an antibody and another protein attached to it that are used in binding to the detection zone and the control zone, respectively.

As to the phrase "can participate" this usage is correct because participation in the control reaction does not occur until sample is applied. Nevertheless, the claim as a whole clearly requires that there be something in the device such that the control reaction between the non-specific protein and the control zone occurs when sample is applied. As explained above, this something is lacking in May.

Finally, the Examiner states that the rejection of claim 5 is maintained because the arguments were "directed to the incorrect form of the claim." (Examiner's Answer, Page 9) This argument is not understood. According to the Examiner's Answer (Page 3), claim 5 should read:

> An assay device according to claim 9, additionally comprising a second population of said direct particulate label sensitised solely with said non-specific protein.

a text which is identical to the text that appeared in the Appendix to the Appeal Brief. Applicants' argument concerning claim 5 stated that:

> claim 5 contains the limitation that the device 'additionally compris[es] a second population of direct particulate label sensitised solely with said non-specific protein.' There is no teaching in May of such a second population of particulate labels. Thus, this claim is not anticipated.

(Appeal Brief, Page 9). Thus, the claim language that appeared in the argument is exactly the language of the claim. The examiner has still not explained where in the May et al. device a population of gold particles with nothing on them but BSA is found, or what use it would have in the May device if it were added.

The withdrawal of the art rejection of claims 10 and 11 is noted.

Conclusion

For these reasons, Applicants submit that this application is allowable, and that the outstanding rejections should all be reversed.

Respectfully submitted,

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